



Testimony

**Before the Subcommittee on Labor/HHS/Education
and Related Agencies
Committee on Appropriations**

United States House of Representatives

Influenza Preparedness

Statement of

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Mr. Chairman and members of the Subcommittee, I am pleased to be here today to discuss the work of the Centers for Disease Control and Prevention (CDC) in the control of influenza: first, by promoting protection against annual outbreaks of influenza, and second, by implementing necessary steps to prepare for the next influenza pandemic. Each year, influenza causes an average of 36,000 deaths in the United States, mostly among the elderly, and over 200,000 hospitalizations. In addition, a global outbreak, or “pandemic” influenza, which has occurred three times during the past century, could have the potential to kill tens of millions of people worldwide. These issues are closely linked, and comprehensive preparedness for annual influenza outbreaks is the basis of an effective response to pandemic influenza. By fortifying the system that supports our efforts in both of these areas, CDC can have a great impact on America’s health and national security.

Today’s testimony will address CDC’s response to the vaccine shortage experienced during the 2004 annual influenza season and our plans for next year. We also provide some background related to annual outbreaks, pandemics, and avian influenza and discuss four primary areas that CDC and the public health system are addressing to ensure that we have the capacity to effectively detect and respond. These four areas are: enhancing our surveillance capacity; increasing vaccine and antiviral supply; increasing vaccination coverage; and strengthening state-based pandemic preparedness planning.

CDC response to 2004 vaccine shortage and plans for next year

As you are aware, Chiron Corporation notified HHS on October 5, 2004 that none of its influenza vaccine would be available for distribution in the United States for the 2004-2005 influenza season. This effectively reduced the anticipated vaccine supply by nearly half—more than 100 million doses had been expected; Chiron was expected to produce 46-48 million doses. Despite the challenges presented by the loss of Chiron's vaccine, CDC immediately responded by changing recommendations to focus vaccine efforts and then began monitoring. State specific flu vaccination data for adults and children were rapidly collected and reported on an ongoing basis from November 2004 through February 2005. CDC's Behavior Risk Factor Surveillance System reported that 62.7 percent of Americans 65 years of age and older reported being vaccinated for influenza between September 2004 and January 2005. This coverage is comparable to the percentage of older Americans vaccinated in previous years without supply shortages. So, many at-risk older Americans were vaccinated as a result of effective work of state and local health departments and the cooperation of younger, healthier Americans who 'stepped aside' for the older and more vulnerable populations allowing us to maximize the utility of the vaccine we had available. In addition, through January of 2005, 48.4 percent of young children (between 6 and 23 months of age) were vaccinated. This marked the highest ever vaccination coverage rate in response to a first-time recommendation of a new vaccine for children.

CDC is now planning for the 2005-2006 influenza season. We anticipate continued challenges in meeting the nation's vaccine supply needs. CDC has identified several scenarios regarding vaccine supply, including possible production shortfalls among current influenza vaccine manufacturers for the U.S. market and/or the entry of new vaccine manufacturers into the U.S. market. We have worked with the Advisory Committee on Immunization Practices (ACIP) to refine prioritization plans should there be another critical vaccine shortage and we have developed possible influenza vaccine supply scenarios that range from worst-case to best-case situations. These scenarios form the basis for CDC planning efforts. In collaboration with the Food and Drug Administration and the National Vaccine Program Office, CDC is meeting with U.S.-licensed and other vaccine manufacturers to discuss plans for the next season, including production and distribution plans and establishing advance vaccine purchase guarantees.

Background: Annual Outbreaks, Pandemics, and Avian Influenza

Complex changes occur in strains of influenza circulating each year. To ensure that the annual influenza vaccine contains strains that most closely match those currently circulating each year, disease-causing strains are collected from across the globe using current surveillance systems. On the basis of these data, advisory groups at the World Health Organization (WHO) and in the United States recommend the strains to be included in each year's vaccine. The technical data and expertise that CDC provides are vital to this process. Global surveillance needs to be enhanced to improve data available for the annual vaccine strain selection process and to provide as early a

warning as possible when a new strain emerges. There are no guaranteed scientific methods to predict which strain will lead to a pandemic, so constant vigilance is critical.

In order for an influenza virus, such as the avian influenza H5N1 strain, to potentially cause a pandemic, it must meet three major criteria: (1) possess a new surface protein to which there is little or no pre-existing immunity in the human population; (2) have the ability for sustained transmission from person to person; and (3) be able to cause illness in humans. Fortunately, the present avian influenza H5N1 strain in Southeast Asia does not yet have the capability of sustained person-to-person transmission, although chicken-to-human transmission has occurred, and in at least two clusters, limited person-to-person transmission has been identified.

Ongoing reports of outbreaks of H5N1 influenza outbreaks in poultry populations indicate that the virus now exists in Southeast Asia. It has also caused illnesses and deaths in humans. Between January 28, 2004 and March 31, 2005, WHO has confirmed 74 confirmed human cases of avian influenza in Southeast Asia, including 49 deaths. New cases are reported almost weekly. CDC is closely monitoring this situation in collaboration with WHO.

Influenza Surveillance

Surveillance is and must be the foundation for all influenza prevention and control activities. Early-warning surveillance activities are being expanded to help detect the next pandemic. Public health professionals are monitoring ongoing changes in the H5N1 strain of avian flu for mutations that may cause increased human infections, as well as monitoring for other viruses with pandemic potential. These actions are paramount in developing prototype vaccine candidates as quickly as possible.

Global Surveillance

Because a pandemic strain can arise anywhere and at any time, expanded global surveillance capacity is needed. The outbreaks of avian influenza in Southeast Asia have highlighted gaps in disease surveillance globally that now are being addressed to improve our ability to prepare for an influenza pandemic. DHHS has made significant contributions and progress in the past year to enhance surveillance in Southeast Asia. CDC's Global Disease Detection Initiative supports the strengthening of our capacity to respond to pandemic influenza. Funding from this resource has been used around the world to increase the number of international public health sites that have the capacity to conduct disease identification and intervention activities, provide critical public health expertise to countries in need, train international collaborators to recognize and respond to influenza and other disease threats, and improve communications capabilities. In FY 2004 CDC allocated \$2.5 million of our global disease detection

funds for avian influenza surveillance. Such activities expand geographic coverage and develop an adequate capacity to conduct effective surveillance. CDC will continue to support the expansion of international surveillance networks and the closing of gaps in information, infrastructure, laboratory and surveillance technology in key areas of the world through the Global Disease Detection program and other international programs at CDC.

Countries affected by avian influenza and their neighbors need increased training and transfer of technology to allow rapid identification and analysis of influenza viruses. Strengthening the capacity of these countries to conduct influenza surveillance allows them to share influenza virus isolates through the WHO surveillance network. These efforts, in turn, increase our ability to detect new variants earlier, make more informed vaccine decisions for annual influenza, and build an early warning system for new virus strains that may cause a pandemic. With the ever-present threat of a new pandemic strain, we need to know what is happening in the barnyards of Southeast Asia, as well as elsewhere throughout the world. Year-round, CDC's worldwide surveillance for new strains of influenza prepares us for next year's epidemic and for the next pandemic.

Domestic Surveillance

In the past year, CDC has also considerably improved domestic surveillance, adding two new major components to our surveillance system. We have worked with the Council for State and Territorial Epidemiologists to make pediatric deaths due to influenza a nationally notifiable disease. In addition, we have implemented hospital-

based surveillance for influenza in children at selected sites and issued interim guidelines to states and hospitals to enhance surveillance for potential cases of people infected by avian influenza. CDC also set up special laboratory training courses for identification of avian influenza using rapid molecular techniques. So far, health professionals from 31 states have been trained, and we plan to train staff from the remaining states in the coming months.

Vaccine and Antiviral Supply and Vaccination Coverage

The best strategy for influenza prevention and control both during annual outbreaks and during a pandemic is vaccination. To fully implement this strategy, we need an ample supply of vaccine, robust demand, and effective vaccination coverage. Antiviral medications are a second line of defense.

The vaccine manufacturing system in the United States is fragile. Currently, there are only three influenza vaccine manufacturers producing vaccines for the US market, and only one of those manufacturers produces its vaccine entirely in the United States. During an influenza pandemic, the presence of US-based manufacturing facilities would be critically important because vaccine produced in other countries may not be available to the US market. CDC has developed several strategies to address potential vaccine shortages. Some strategies support enhanced vaccine production, while others work to ensure vaccine is distributed to populations with the greatest need.

For the first time, we have created stockpiles of both influenza vaccine and antiviral medications. DHHS initially budgeted \$40 million in FY 2004 to develop a strategic reserve of influenza vaccine licensed for use during the 2004-2005 influenza season through the Vaccines for Children program, and has budgeted another \$40 million in new money in FY 2005 to develop a strategic reserve of influenza vaccine licensed for use during the 2005-2006 influenza season.

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In the event of a pandemic, there would be limited time to test, produce, and administer vaccine. CDC estimates that it would take several months for the first dose of pandemic vaccine to be ready and longer to manufacture enough to vaccinate the entire U.S. population. In FY 2004 DHHS invested \$13 million in the development and production of two million doses of H5N1 vaccine to prepare our nation for a potential influenza H5N1 pandemic.

One of the greatest challenges in vaccine planning is the year-to-year unpredictability of public demand for influenza vaccine, which makes manufacturers reluctant to produce large amounts of the vaccine. Increased and stable public demand for influenza vaccine on a yearly basis would allow companies to have a predictable market and provide them with incentive to increase production. There is an emerging consensus that it is desirable to expand vaccine coverage recommendations to include people beyond high priority groups for whom routine vaccination is already recommended. Research is under way to determine how broad the recommendations for influenza vaccination

should be. Meanwhile, CDC is developing strategies to increase demand for, and access to, influenza vaccine for persons who are currently recommended to be vaccinated.

The President's Budget Request for FY 2006 includes provisions to help protect against annual shortages of influenza vaccine in the US. The request includes an additional \$40 million in new money for purchasing influenza vaccine for the Vaccines for Children Program stockpile. The FY 2006 request also includes increases for the Immunization Grant Program (Section 317). The first initiative calls for an increase of \$30 million to allow CDC to enter into sales guarantee contracts with manufacturers to ensure the creation of more vaccine for upcoming influenza seasons by expanding the production of bulk monovalent (single strain) influenza vaccine. The second increase in the FY 2006 request is \$20 million to ensure that states have access to additional influenza vaccine. The investment will increase influenza vaccination coverage for children to reduce the burden of annual influenza and further improve the infrastructure for an influenza pandemic.

The request also includes a proposed change in the law for VFC to allow underinsured children to receive VFC vaccine at approximately 7,000 state and local public health clinics. Thus, access points will be expanded for underinsured children beyond rural health centers and federally qualified health centers.

State-based Pandemic Influenza Preparedness Planning

States have a major role in the event of a pandemic and are preparing for it by developing pandemic influenza plans or revising existing plans to be stronger and more effective. The key elements of these plans include surveillance, vaccination, antiviral drug use, community containment measures, communications, response of the health care system, and ability to maintain essential public services. CDC is developing detailed guidance and materials, including information on who should be included in priority groups for both vaccine and antiviral distribution, to assist states in creating these plans.

Containment Measures

If a pandemic strain starts circulating in the United States, isolation precautions for persons who are ill and quarantine for healthy but exposed persons may be considered as part of state actions that may be needed to limit the spread of pandemic influenza, particularly before a vaccine becomes available. Measures such as these would require a multi-level, multifaceted, staged process and would involve tribal, state, and federal authorities. Steps such as evaluating all ill travelers arriving from affected areas, adding pandemic influenza to the list of quarantinable diseases by Presidential Executive Order, and implementing a series of travel notices to minimize outbreaks extending to wider geographic areas may be needed. CDC is preparing for this potential need by expanding the number and capacity of its quarantine stations at major ports of entry into

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the United States. As with any quarantine, such activities need to be undertaken judiciously to minimize adverse impacts on civil liberties.

Collaboration with other Agencies

CDC has created extensive partnerships with other DHHS agencies, other federal agencies, provider groups, non-profit organizations, and state and local health departments to enhance pandemic and annual influenza planning and to improve the balance between vaccine supply and demand. CDC is collaborating with the National Institutes of Health, the National Vaccine Program Office, the Food and Drug Administration, the Health Resources Services Administration, the Centers for Medicare and Medicaid Services, and others involved with the DHHS Draft Pandemic Influenza Response and Preparedness Plan to address critical decisions and actions needed at the federal and state levels. CDC welcomes the opportunity to work more extensively with other DHHS agencies and agencies throughout the government on these important issues.

Conclusion

CDC's response to the annual domestic influenza season continually informs the nation's planning and preparedness for pandemic influenza. The same laboratories, health care providers, surveillance systems, health department plans, and personnel guide both responses. The importance of prompt action to support surveillance, adequate vaccine supply, enhanced vaccination coverage, and state-based planning is made urgent by the current avian influenza situation in Southeast Asia and the potential threat it poses to become pandemic influenza. Today I have outlined CDC's progress and I have pointed out the challenges we face to ensure that the United States protects its public from the morbidity and mortality related to annual influenza and plays a key role in global and domestic pandemic preparation. Thank you for this opportunity to share this information with you. I am happy to answer any questions.